A Dose of Clear Directions for Rx Drug Users

More than four centuries ago, doctors were considered omnipotent, and the ethical statutes of England's Royal College of Physicians instructed: "Let no physician teach the people about medicines, or even tell them the names of the medicines, particularly the more potent ones ... for the people may be harmed by their improper use."

While doctors today are more forthcoming, many patients still have a hard time getting important information about the drugs their doctors prescribe. In a time when Corn Flakes, over-the-counter Tylenol, and even Alpo dog food come with easy-to-understand information about proper use, many prescription drugs still come with only a "Use as Directed" sticker for patients. The rest of the labeling is for the medical professional, in language that may be difficult for lay people to understand.

This lack of information for patients may be one reason for the finding, published in 1992 in the *Journal of Clinical Pharmacy and Therapeutics*, that about half of prescription drugs don't work as intended because they are improperly used.

Noncompliance can have tragic consequences. Missed doses of heart medications, for example, may lead to cardiac arrest. And missed doses of antiglaucoma medicines can lead to eye nerve damage and blindness.

To help avoid medication problems, a new "Action Plan for the Provision of Useful Medicine Information" was unveiled in January 1997 to provide more and better information to patients.

Simple, Relevant Information

Under the action plan, health professionals will voluntarily provide prescription drug information to patients in the form of leaflets written in simple language.

Useful prescription drug information must reach at least 75 percent of patients by the year 2000, in keeping with the Department of Health and Human Services goal under its Healthy People 2000 program. By 2006, the information must reach at least 95 percent of patients. If these goals aren't met, FDA may require the information by regulation.

The plan was developed with the input of health professionals and consumer, government, and industry representatives.

"Working together and using today's computer technology," said Secretary of Health and Human Services Donna Shalala when she approved the plan, "we can make prescription information more widely available, more understandable, and more relevant for each individual patient."

The action plan calls for the written information to include the condition(s) for which the drug is used,

Prescription Drug Information

Cefaclor

Why is Cefaclor prescribed?

Cefaclor is used to treat infections caused by certain bacteria. These infections include middle ear, bladder, and skin infections, as well as strep throat and pneumonia. Cefaclor works by killing certain bacteria or preventing them from growing. It works only for certain bacteria and not for others. Cefaclor is in a class of drugs known as cephalosporin antibiotics. Medicines are sometimes prescribed for uses other than those listed in this leaflet. If you have any questions please call your doctor or other prescriber.

Before Taking Your Medicine

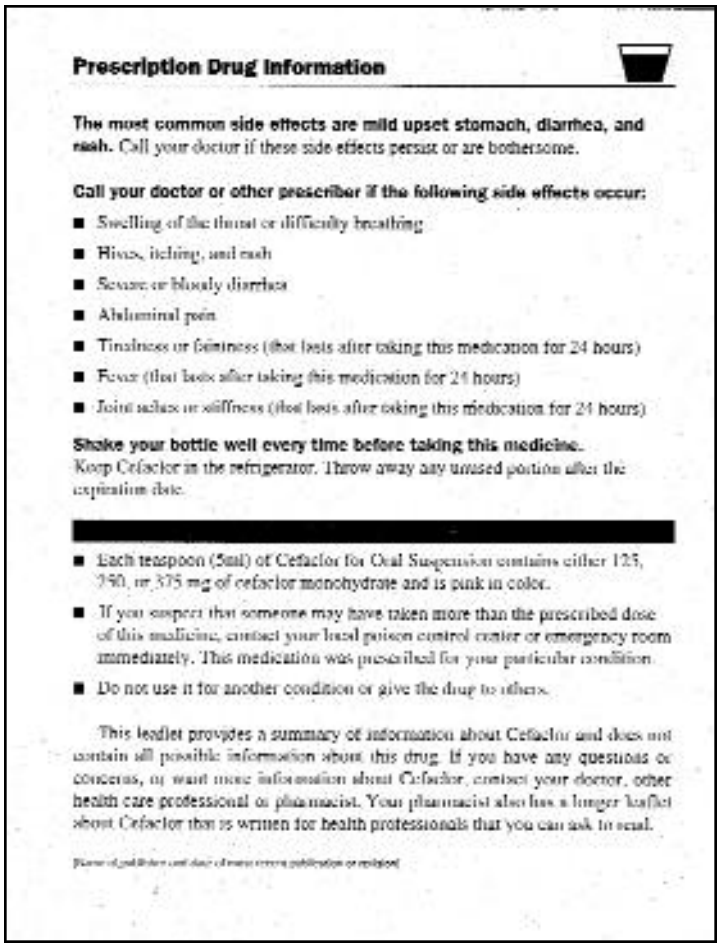
Check with your doctor or other prescriber. This medication may not be right for you, if you:

- **have abdominal problems**
- **are pregnant**
- **are nursing**
- **are a diabetic and checking your urine for sugar:** Cefaclor can interfere with the urine test you may be using to test for sugar.
- **are taking other medications:** Do not take this drug if you are allergic to penicillin or any other cephalosporin-class antibiotic because it is likely that you may also be allergic to Cefaclor.

While You Are Taking Your Medicine

Continue taking Cefaclor even if you feel better. Be sure to take all of the medication for the length of time prescribed for you. If you stop taking your medication too soon, the bacteria can grow back and you may get sick again with the same infection.

- If you miss taking a dose of Cefaclor, take it as soon as you remember.
- If it is almost time for your next dose, skip the missed dose and take your medicine as scheduled.
- Do not take double your prescribed dose.



Prescription Drug Information

The most common side effects are mild upset stomach, diarrhea, and rash. Call your doctor if these side effects persist or are bothersome.

Call your doctor or other prescriber if the following side effects occur:

- Swelling of the throat or difficulty breathing
- Hives, itching, and rash
- Severe or bloody diarrhea
- Abdominal pain
- Tiredness or faintness (that lasts after taking this medication for 24 hours)
- Fever (that lasts after taking this medication for 24 hours)
- Joint aches or stiffness (that lasts after taking this medication for 24 hours)

Shake your bottle well every time before taking this medicine. Keep Cefaclor in the refrigerator. Throw away any unused portion after the expiration date.

- Each teaspoon (5ml) of Cefaclor for Oral Suspension contains either 125, 250, or 375 mg of cefaclor monohydrate and is pink in color.
- If you suspect that someone may have taken more than the prescribed dose of this medicine, contact your local poison control center or emergency room immediately. This medication was prescribed for your particular condition.
- Do not use it for another condition or give the drug to others.

This leaflet provides a summary of information about Cefaclor and does not contain all possible information about this drug. If you have any questions or concerns, or want more information about Cefaclor, contact your doctor, other health care professional or pharmacist. Your pharmacist also has a longer leaflet about Cefaclor that is written for health professionals that you can ask to read.

[Name of publisher and date of most recent publication or revision]

Under the action plan, patients will get leaflets similar to the one above with each prescription drug. The leaflets will explain in simple language how to use the medication correctly.

directions for taking the drug correctly, and possible side effects. Doctors or pharmacists can add information about an "off-label" use—a use that is not approved by FDA—if it is written based on an individual patient's needs.

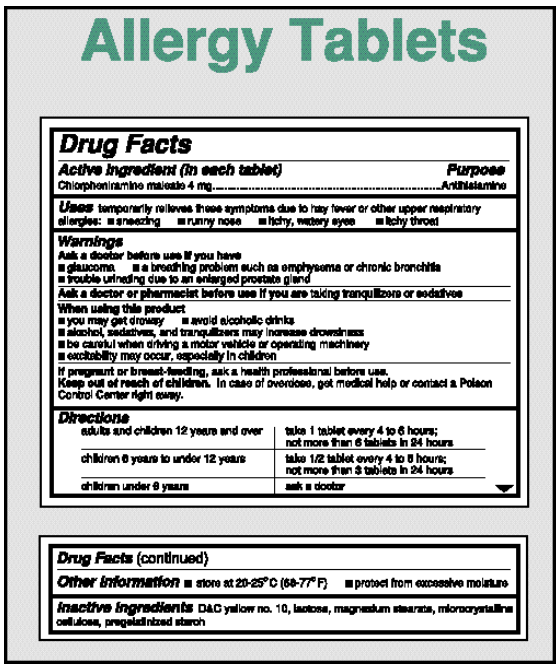
Health professionals are responsible for getting the information to patients. FDA is available for technical assistance and will work to educate the public about the plan, according to Thomas McGinnis, a pharmacist and FDA's deputy associate commissioner of health affairs.

FDA will survey consumers nationwide in the year 2000 and again in 2006 to determine if the goals have been met. The agency will evaluate samples of the patient labeling to make sure it provides the required information in simple language. (See "Is the Labeling Useful?" p. 91).

FDA has tried before to provide prescription medicine information to consumers. A rule the agency proposed in 1979 would have required manufacturers to include leaflets known as patient package inserts, or PPIs, with 10 prescription drugs or drug classes. The rule was withdrawn in 1982 to allow private organizations time to provide the information voluntarily.

In the next decade, FDA research showed minimal progress in getting good-quality medication information to patients. So, in 1995, FDA proposed a rule, commonly called MedGuide, that set forth goals for the distribution of useful prescription drug information to consumers and would have required manufacturers to include drug information for the patient when a product posed a serious health risk.

In August 1996, Congress passed legislation that put the MedGuide proposal on hold to provide another opportunity for private achievement of the MedGuide goals. The action plan is the private sector's framework for achieving those goals.



Lack of Labeling

Prescription drugs with a label saying only "Take As Directed" may soon be a thing of the past, thanks to the new "Action Plan for the Provision of Useful Medicine Information." The plan will give consumers the kind of easy-to-understand information that they already get when they buy over-the-counter drugs or food.

Currently, manufacturers provide patient information for about 40 prescription drugs or drug classes. FDA requires patient information for some drugs, including oral contraceptives and isoproterenol inhalation products used by asthmatics. Manufacturers voluntarily provide FDA-reviewed patient labeling with some other products, such as Accutane (isotretinoin) for acne and Halcion (triazolam) for insomnia.

A 1997 FDA survey found that 67 percent of consumers were getting some written information with their prescription drugs, up from 54 percent in 1994.

But the surveys don't take into consideration the quality of the information. "The materials being given to consumers are very variable," McGinnis says. "Some are very poor, some are very good, and some are in-between. Most of the information out there now is going to have to be beefed up to meet the action plan criteria."

By increasing patients' knowledge about their drug therapies, the action plan aims to help patients take their drugs correctly. Improper use of prescription drugs leads to unnecessary illnesses, emergency room visits, hospital admissions, and deaths. FDA estimates extra healthcare costs from preventable drug-related illnesses to be at least $20 billion a year. (See "Medication Mishaps.")

In addition to instructions for proper use, the information sheets will address a drug's risks and side effects, according to McGinnis. By telling patients what to look for and what to do if they see warning signs, the information may help patients recognize side effects earlier, before serious damage is done.

"These drugs are risky—they wouldn't be prescription drugs if they weren't—and patients have a right to know what the risks are," McGinnis says.

Some groups representing the pharmaceutical industry and health professionals have expressed concern to FDA that informing patients of risks and side effects may hurt compliance by scaring consumers out of taking the drug as prescribed. To this, McGinnis replies, "We've heard that argument, but we've never seen it supported scientifically."

Empowering the Patient

Written information sheets cannot replace the advice of a health professional. But there are some barriers to communication between patients and health professionals, according to David Schulke, director of policy and regulatory affairs at the American Pharmaceutical Association. "There are financial pressures that cause doctors and pharmacists to talk to more patients in less time, giving less time to each patient."

Because of the competing demands on health professionals' time, written

information is especially important. "The piece of paper becomes a back-up, a safety net that patients can keep with them and refer to for information," says consumer advocate Arthur Levin, director of the Center for Medical Consumers.

Patients sometimes need to take on a very active role in their own healthcare, according to McGinnis. "FDA is hoping the additional information will help the patient feel less inhibited about asking questions," he says. "We hope it will encourage patients to become more involved, along with their physician, pharmacist, or nurse."

Medication Mishaps

Accupril and Accutane. The drug names sound pretty similar, but they are prescribed for very different conditions. Accupril (quinapril hydrochloride) is used to treat high blood pressure and heart failure. Accutane (isotretinoin) is for certain types of severe acne.

You wouldn't want to take Accutane for a heart condition by mistake. But a patient could be given the wrong drug by accident. Confusion can arise from similar drug names or packaging, a prescriber's poor handwriting, misinterpretation of an abbreviated drug name, or an incorrect data entry into a computer.

To prevent avoidable accidents, FDA's Center for Drug Evaluation and Research compares drug names to see if a change is needed to avoid confusion.

"FDA's goal is to try to catch the potential for error before the product is marketed," says Sharon Smith Holston, FDA's deputy commissioner for external affairs. "Later, if we get reports of errors, we will work with the manufacturer to correct the problem by making a change in the packaging, labeling, or name."

Patients themselves can prevent certain types of drug errors. The National Council on Patient Information and Education recommends asking your health professional at least these six questions about a prescription medication:

- What is the name of the medicine and what is it supposed to do?
- How and when do I take it, and for how long?
- What foods, drinks, other medicines, or activities should I avoid while taking this medicine?
- Are there any side effects, and what should I do if they occur?
- Will this new prescription work safely with the other prescription and nonprescription medicines I am taking?
- Is there any written information available about the medicine?

Patients who get drug information in writing as well as orally, says FDA pharmacist Thomas McGinnis, are much more likely to notice if the drug they got isn't for the condition they went to the doctor about or if it may be dangerous if taken with certain foods or another medication.

If a medication error occurs or is suspected, a health professional may report it, in confidence, to FDA's MedWatch program at (1-800) FDA-0178 or the U.S. Pharmacopeia's Medication Errors Reporting Program at (1-800) 23-ERROR.

Is the Labeling Useful?

To be acceptable under the action plan, the information given to patients must be scientifically accurate, unbiased, specific, complete, understandable, up-to-date, and useful.

"The criteria aren't set in stone," says FDA pharmacist Thomas McGinnis. For example, the format may have to be adjusted for some populations. For the elderly, whose eyesight may be declining, the type may have to be larger.

How will FDA determine if labeling is "useful"? The agency will look for specific information, including:

- Medicine name;
- Critical warnings (prominently displayed);
- Conditions for which the product is used;
- Circumstances under which the product shouldn't be used and directions about what to do if one of these circumstances applies (for example, "Talk to your healthcare professional before taking this medication if any of these apply to you.");
- Drugs, foods and activities that should be avoided while taking the medication, and other precautions necessary to take the medicine properly;
- Symptoms of adverse reactions possibly related to the drug;
- Risk, if any, of developing a drug tolerance or dependence;
- Instructions for proper use, including the usual doses, instructions if a scheduled dose is missed, special instructions (for example, whether to take with food or water), and what to do in case of an overdose;
- Storage instructions;
- General information, including a statement encouraging discussion with a healthcare professional and a statement that the drug should not be given to others; and
- A statement that the patient labeling does not contain all possible information about the medicine and that the healthcare professional has more information.

To obtain a copy of the action plan, access the Keystone Center's Website at http://www.nyam.org/keystone/ or call (202) 783-0248. To obtain more information about the action plan, contact FDA Office of Consumer Affairs HFE-88, 5600 Fishers Lane, Rockville, MD 20857; tel. 1-888 INFO-FDA (10 a.m. to 4 p.m. Eastern time, Monday through Friday).